OCT 3 0 2003

510(k) Summary of Safety and Effectiveness

K031473

Submitted by

Intuitive Imaging Informatics, LLC
30 Hackamore Lane Suite 4
Bell Canyon, CA 91307-1061

818-347-8919 (phn)
818-347-8909 (fax)

29 April 2003

K031473

Per Title 21 CFR 807 . 92, the following is the 510(k) Summary for the Rational Imaging PACS manufactured and marketed by Intuitive Imaging Informatics, LLC under the trade-name .

(1) SUBMITTER:

Intuitive Imaging Informatics, LLC
30 Hackamore Lane Suite 4
Bell Canyon, CA 91307-1061

818-347-8919 (phone)
818-347-8909 (fax)

CONTACT:

Donald Mundt
Manager, Regulatory Affairs
Intuitive Imaging Informatics, LLC
30 Hackamore Lane Suite 4
Bell Canyon, CA 91307-1061

818-347-8919 (phone)
818-347-8909 (fax)

SUBMISSION DATE: 29 April 2003

(2) DEVICE NAME:

TRADE NAME: Rational Imaging PACS

COMMON NAME: Image Processing system

CLASSIFICATION NAME: (per regulation 21 CFR 892.2030) (Class II device)
Picture Archiving and Communication System

PRODUCT CODE: LLZ

(3) PREDICATE DEVICE:

Intuitive Imaging Informatics claims Substantial Equivalence to the following device:

Manufacturer	Trade Name	510(k) Number	Decision Date
Algotec Systems Ltd.	MediSurf	K971347	07-03-1997

(4) DEVICE DESCRIPTION:

Rational Imaging PACS is designed for use by a physician or other medical professionals in the acquisition of medical images and demographic detail from all institutional imaging modalities, including CT, CR, MRI, NM, DR, US, Angio, nuclear medicine, and secondary capture devices

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such as film digitizers or other imaging sources.. The acquired medical images and demographic information may be displayed, processed, reviewed, sent to and retrieved by radiologists at remote sites, stored, archived or printed. Multi-planar Reconstruction (MPR), Anatomic Triangulation (AT) and 3D display are optionally available.

(5) INTENDED USE OF DEVICE

The Rational Imaging PACS is intended to be used in a Radiological Laboratory or Doctors office to allow the medical professionals to retrieve and review exam images at various rotations and options, add patient identification and compress the image using industry accepted techniques. Lossy and lossless compressed images are encapsulated in DICOM v3.0 format, which then may be transmitted via various communication protocols to other sites or archived by a PACS host.

(6) SUBSTANTIAL EQUIVALENCE TO PREDICATE DEVICE

The proposed Rational Imaging PACS, with MPR, AT options, and the predicate device MediSurf are both software suites that process DICOM compliant images and provide a standard set of features pertaining to image processing, archiving and networking. The image manipulation tools and storage techniques are essentially comparable. Workstations are technologically the same with some differences in media type for archival storage. Compression algorithms are different but accomplish the same results. Both products operate on commercially available equipment and are available as either a hardware/software package or software only.

(7) SAFETY

The potential hazards are identified and controlled by a risk management plan. The plan consists of a risk management summary, a software development and validation process, a software verification plan and conformance to Federal Regulations and Industry Standards.

(8) CONCLUSION

The Rational Imaging PACS DICOM compliant imaging system acquires, processes, archives and distributes images over the Internet utilizing similar techniques and functions as the predicate device MediSurf.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2003

Mr. Donald Mundt
Manager, Regulatory Affairs
Intuitive Imaging Informatics, LLC
30 Hackamore Lane, Suite 4
BELL CANYON CA 91307-1061

Re: K031473
Trade/Device Name: Rational Imaging PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 2, 2003
Received: September 4, 2003

Dear Mr. Mundt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K031473

Device Name: Rational Imaging PACS

Indications for Use

Rational Imaging PACS is intended for use by a physician or other medical professionals in the acquisition of medical images and demographic detail from all institutional imaging modalities, including CT, MRI, NM, DR, US, nuclear medicine, Angio and secondary capture devices such as film digitizers or other imaging sources. The acquired medical images and demographic information may be displayed, processed, reviewed optionally utilizing Multi-planar Reconstruction (MPR), Anatomic Triangulation (AT) and 3D display, sent to and retrieved by radiologists at remote sites, stored, archived or printed.

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031473

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)